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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/17/2004

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EXAMINER

LISTVOYB, GREGORY

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,859	Applicant(s) INOUE ET AL.	
	Examiner GREGORY LISTVOYB	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44,47-71,74 and 77-135 is/are pending in the application.
- 4a) Of the above claim(s) 77-130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 43,44,47-71,74 and 131-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 43, 44, 47-71, 74 and 131-135 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biodegradable moldable resin based on polylactic acid, polybutylene succinate and few others, does not reasonably provide enablement for any other biodegradable moldable resin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court In re Wands, 8 USPQ 2d 1400 (CA FC 1988). Wands states at page 1404, the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working example and (8) the quantity of experimentation necessary.

The nature of the invention and breadth of claims

The claimed invention is a thermo reversible biodegradable moldable resin

This substance is enabled only for a few kinds of materials, such as polylactic acid and polybutylene succinate, described in Examples 1-12.

Therefore, the scope of the Claims ("A biodegradable moldable resin", meaning any biodegradable resin) is much broader than one disclosed in the Specification.

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The state of the prior art

In the prior art to Chen et al (US patent 6018033 as discussed below, discloses a a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples I1-1, II1-1 and 111-2).

The above reference provides teaching based only on a limited classes of biodegradable resin.

Therefore, Chen reference represents only a limited teaching of resins, which have thermo-reversible Diels-Alder bonds.

The amount of direction or guidance presented:

The Applicant does not provide any teaching regarding other thermo-reversible biodegradable resins. In Examiner's position, this teaching would be necessary, considering that those resins have broad range of structures, which can lead to wide variety of property sets, require different reaction systems, needed to create thermo-reversible Diels-Alder linkages.

The presence or absence of working example:

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The Applicant presents working Examples based on only two types of resin, such as polylactic acid and polybutylene succinate. There is no working Examples, related to any other polyimide type.

The quantity of experimentation necessary.

2. It is concluded that it would have require undue experimentation for one having ordinary skill in the art to practice the claimed invention to find appropriate step to expand the applicant's teaching to any other type of polyimide besides one based on polylactic acid and polybutylene succinate.

In re Wands, 858, F.2d at 737, 8 USPQ 2d 1400, 1404 (Fed Cir. 1988)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 44, 47-71, 74 and 131-135 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A term Diels-Alder type is inappropriate, since it is not clear, where Applicant claims Diels-Alder link or some other group, which can provide thermo-reversible linkage.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-44, 47-48, 51-53, 55-57, 59-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US patent 6018033), (cited in the previous Office Action) in view of Ruben (US 6146655)

Regarding Claims 43-44, 47-48, 53, 57, 60, 61, Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II-1 and III-2 and Column 7, line 35).

Regarding Claim 52, Chen teaches a biodegradable resin can contain linear and branched structure (column 5, line 25).

Regarding Claims 51, 55 and 59, Chen discloses cross-linked density in terms of Swelling Ratio. This ratio changes within a broad range of 5-90%. According to Flory, cross-link frequency can be calculated from the above parameter (more crosslink frequency corresponds with less swelling ratio). In examiner's opinion, Chen's

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composition internally possesses cross-linked density to meet the limitations of the above Claims.

Chen does not teach that his composition is moldable.

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

The advantage of Ruben is that the above gel can be molded in the shape of water –permeable porous envelope (see Abstract), which can be used in oral applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60).

Therefore, it would have been obvious to a person of ordinary skills to use Chen's polysaccharides in moldable drug delivery compositions, since it allows increasing applicability of the material.

Claim 49, 54 and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in combination with Ruben and Helmus et al (US publication 2004/0093080 and WO 0154745) (cited in the previous Office Action)

Chen discloses a modified Saccharine, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples I1-1, II1-1 and 111-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II1-1 and 111-2 and Column 7, line 35).

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

The advantage of Ruben is that the above gel can be molded in the shape of water –permeable porous envelope (see Abstract), which can be used in oral applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60).

Chen or Ruben does not disclose a biodegradable resin based on polylactic acid.

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as chen's one.

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Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945), 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

It would be obvious to a person with ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material are known material based on its suitability for its intended use.

Claims 43, 47, 48, 58, 62 and 71-74 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in combination with Ruben and Kozo (JP publication 2000-28105) (cited in the previous Office Action).

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C.

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

The advantage of Ruben is that the above gel can be molded in the shape of water –permeable porous envelope (see Abstract), which can be used in oral applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60).

Chen or Ruben does not teach ion-crosslinking compositions.

Kozo discloses polysaccharide-based ion-crosslinking film and its production (Abstract). Kozo teaches that in order to create ion-crosslinking polysaccharide composition divalent ions added to the composition. It allows to increase amount of applications for Chen's composition, regulating the number of cross-links not only by temperature, but also ionic strength. It can be especially useful in *in vivo* applications, where drug delivery composition targets specific organ.

Therefore, it would be obvious to a person with ordinary skills in the art to add ion-crosslinking polysaccharide fragments to Chen's composition to create both covalent and ionic reversible crosslinked structure. It would diversify a number of applications for Chen's composition. For instance, such composition can be used in drug delivery systems and other *in-vivo* applications.

Claims 131-133 and 135 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US patent 6018033), (cited in the previous Office Action) in view of Ruben (US 6146655) and Weissler et al (WO 2002/016378, cited with equivalent US 2004/0059101)

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II-1 and III-2 and Column 7, line 35).

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

Chen or Ruben do not teach cyclic dienes as Diels-Alder reagents.

Weissler teaches biodegradable reversible system (see line 0008), based on polysaccharide (see line 0011) and cyclic or acyclic diene (see line 0006). Weissler teaches that the above reagents produce a compound with well controlled structure and

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quantitative yield (see line 0008). Also, Weissler discloses that the reaction can be performed at mild conditions (see line 0008).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to interchangeably use cyclic and alicyclic dienes in Chen's composition, modified with Ruben, since these compounds are known material based on its suitability for its intended use.

Note that both Weissler and Chen apply their compound for drug delivery system and other medical purposes (see line Weissler, line 0002 and Chen, Col27, line 30).

Allowable Subject Matter

Claim 50, 67-70,134 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Prior art, which discloses thermo-reversible Diels-Alder composition based on polybutylene does not found in the Prior Art.

The closest Prior Art reference is Chino (US patent 6746562 and equivalent JP2002-2060422, both cited in the previous Office Action).

Chino teaches a thermo reversible resin, based on succinic acid and succinic anhydride (Column 27, line 30)

However, Chino does not teach Diels –Alder system and polybutylene succinate (PBS).

Response to Arguments

Applicant's arguments with respect to claims 43-44, 47-71, 74, 131-135 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rabon Sergent/
Primary Examiner, Art Unit 1796

GL

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